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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,252	03/01/2002	Peter Leskovar	07038.0003U2	5111
23859	7590	07/14/2004	EXAMINER	
NEEDLE & ROSENBERG, P.C. SUITE 1000 999 PEACHTREE STREET ATLANTA, GA 30309-3915			NICKOL, GARY B	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/087,252

Applicant(s)

LESKOVAR, PETER

Examiner

Gary B. Nickol Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 2-6 and 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 7 and 9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☒ Certified copies of the priority documents have been received in Application No. 08/808,334.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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Re: Leskovar, P.

Date of priority: 04/15/1988

The Election filed 05/03/04 in response to the Office Action of 04/01/04 is acknowledged and has been entered.

Applicant's election with traverse of Group I, claims 1, 7, 9 is acknowledged. The traversal is on the ground(s) that a search and examination of all of the inventions would not impose a serious burden on the examiner. This is not found persuasive.

Although the inventions are classified somewhat similarly, the classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not coextensive and is much more important in evaluating the burden of search. For example, there are a multitude of different antibodies in Group I that would require independent searching separate from the other Groups. Different searches and issues are involved in the examination of each group. For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

Claims 1, 7 and 9 are currently under consideration.

Claims 2-6, and 8 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions.

***Declaration***

The declaration filed under 37 CFR 1.132 filed 03/01/2002 has been received and has been entered into the record.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosenberg *et al.* (Science, Vol. 233, September 1986, pages 1318-1321).

Rosenberg *et al.* teach a method for treating cancer in a subject comprising eliminating suppressor cells in the subject (via the administration of cyclophosphamide), preactivating lymphocytes from the subject *ex vivo*- wherein the lymphocytes of the subject are pre-activated by contacting the lymphocytes *ex vivo* with tumor cells from the subject (column 2, page 1319), and injecting the pre-activated lymphocytes into the subject, thereby treating the cancer. Further, as evidenced by Mastrangelo *et al.* (Seminars in Oncology, Vol. 13, No. 2, 1986, pp 186-194), cyclophosphamide is selectively cytotoxic for suppressor T cells and their precursors (page 190, 2<sup>nd</sup> column, last paragraph).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 7, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg *et al.* (Science, Vol. 233, September 1986, pages 1318-1321) in combination with the teachings of Berd *et al.* (Cancer Research, Vol. 47, May 15, 1987, pages 2727-2732).

Rosenberg *et al.* teaches as set forth above with regards to Claims 1 and 9.

Rosenberg *et al.* do not specifically include the addition of a monoclonal or polyclonal antibody that recognizes suppressor cells (Claim 7).

Berd *et al.* teach the administration of a monoclonal antibody (anti-Leu 2a) which specifically recognizes and substantially depletes suppressor cells in vivo with modest toxicity (page 2727, 2<sup>nd</sup> column, 1<sup>st</sup> paragraph).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to optimize the methods of Rosenberg *et al.* by including an additional agent that aids in the removal of suppressor cells from subjects with cancer. One would have been motivated to do so because Rosenberg *et al.* successfully teaches the treatment of cancer in-vivo comprising adoptive immunotherapy in conjunction with an agent that eliminates suppressor cells while Berd *et al.* teaches an agent (a monoclonal antibody) that results in the marked depletion of circulating suppressor lymphocytes. Moreover, Berd *et al.* provides a nexus for

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using agents that eliminate suppressor cells in combination with adoptive immunotherapy wherein Berd teaches that adoptive therapy with immune lymphocytes can eradicate tumors if suppressor cells have been deleted by whole body radiation or administration of cyclophosphamide (page 2731, 2<sup>nd</sup> column, line 1+). Thus, by combining cyclophosphamide with the monoclonal antibody of Berd *et al.*, one of ordinary skill in the art would have a reasonable expectation that the combination of the two agents would result in the removal of more suppressor cell activity resulting in an increased anti-tumor and or therapeutic response to adoptive immunotherapy.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835.

The examiner can normally be reached on M-Th, 8:30-5:30; alternate Fri., 8:30-4:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary B. Nickol Ph.D.  
Primary Examiner  
Art Unit 1642

GBN  
July 9, 2004

  
**GARY B. NICKOL, PH.D.**  
**PRIMARY EXAMINER**